TAMOXIFEN CITRATE- tamoxifen citrate tablet, film coated
Cadila Healthcare Limited

Tamoxifen Citrate Tablets, USP

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1184-1 in bottle of 100 tablets

Tamoxifen Citrate Tablets USP, 10 mg

Rx Only

100 tablets

NDC 70771-1185-1 in bottle of 100 tablets

Tamoxifen Citrate Tablets USP, 20 mg

Rx Only

100 tablets

TAMOXIFEN CITRATE

tamoxifen citrate tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1184
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TAMOXIFEN CITRATE (UNII: 7FRV7310N6) (TAMOXIFEN - UNII:094ZI81Y45)	TAMOXIFEN	10 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	7mm
Flavor		**Imprint Code**	826
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1184-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
2	NDC:70771-1184-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
3	NDC:70771-1184-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
4	NDC:70771-1184-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206694	01/03/2018	

TAMOXIFEN CITRATE

tamoxifen citrate tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1185
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
TAMOXIFEN CITRATE (UNII: 7FRV7310N6) (TAMOXIFEN - UNII:094ZI81Y45)	TAMOXIFEN	20 mg

Inactive Ingredients	
Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	9mm
Flavor		Imprint Code	827
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1185-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
2	NDC:70771-1185-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
3	NDC:70771-1185-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
4	NDC:70771-1185-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
5	NDC:70771-1185-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206694	01/03/2018	

Labeler - Cadila Healthcare Limited (918596198)

Registrant - Cadila Healthcare Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		863362789	ANALYSIS(70771-1184, 70771-1185) , MANUFACTURE(70771-1184, 70771-1185)

Revised: 7/2020 Cadila Healthcare Limited